

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

HERBERT FUSSMAN,)
INDIVIDUALLY AND AS)
ADMINISTRATOR OF THE ESTATE)
OF RITA FUSSMAN)

Plaintiff,)

v.)

1:06CV149

NOVARTIS PHARMACEUTICALS)
CORPORATION,)

Defendant.)

ORDER AND MEMORANDUM OPINION

BEATY, Chief Judge.

This matter is presently before the Court on Defendant's Motion to Preclude Plaintiff's Demand for Punitive Damages [Doc. # 57]. Defendant filed its Motion pursuant to the Court's Scheduling Order of February 25, 2010. Defendant asks the Court to preclude punitive damages on the grounds that Plaintiff cannot show, by clear and convincing evidence, that there exists a genuine issue of material fact giving rise to a claim of punitive damages. The Court enters the present Order and Memorandum Opinion with respect to the Motion to Preclude Plaintiff's Demand for Punitive Damages.

I. BACKGROUND

This case involves claims by Herbert Fussman, individually and as the Administrator of the Estate of Rita Fussman ("Plaintiff"), against Novartis Pharmaceuticals Corporation

(“Defendant” or “Novartis”) related to injuries suffered by Mrs. Fussman allegedly caused by Defendant’s prescription drugs Aredia and Zometa. In 2001, Mrs. Fussman began receiving infusions of bisphosphonate drugs, specifically Aredia first and later Zometa. Mrs. Fussman continued regular monthly treatments of Zometa through June 2005, with a one month break in her treatment in October 2004. Plaintiff contends that bisphosphonates, including Aredia and Zometa, can cause bisphosphonate-related Osteonecrosis of the Jaw (“ONJ”), and that the Aredia and Zometa taken by Mrs. Fussman was the proximate cause of her ONJ. Plaintiff also contends that Defendant failed to adequately warn Mrs. Fussman and her medical providers of the risk of ONJ associated with Aredia and Zometa.

This case was originally filed in this Court on February 13, 2006 and was thereafter transferred to the Middle District of Tennessee Multi-District Litigation (“MDL”) related to Aredia/Zometa claims. After discovery concluded in the MDL Court, Defendant filed Motions for Summary Judgment with the MDL Court. On August 13, 2009 the MDL Court entered an Order denying Defendant’s Motions for Summary Judgment finding that “there are genuine issues of material fact as to the adequacy of Defendant’s warnings.” As a result, the case was remanded back to this Court for trial, which is scheduled to begin on November 1, 2010. The MDL Court did not specifically address the matter of punitive damages in this case prior to remanding the case back to this Court.

II. SUMMARY JUDGMENT AND PUNITIVE DAMAGES STANDARDS

In support of its Motion, Defendant alleges that Plaintiff has failed to show that there exists a genuine issue of material fact giving rise to a claim for punitive damages in this case, thus

requiring the Court to examine whether Plaintiff's evidence is sufficient to overcome the summary judgment standard. Summary judgment is appropriate when there exists no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Zahodnick v. Int'l Bus. Machs. Corp., 135 F.3d 911, 913 (4th Cir. 1997). The party seeking summary judgment bears the burden of initially coming forward and demonstrating the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265 (1986). Once the moving party has met its burden, the non-moving party must then affirmatively demonstrate that there is a genuine issue of material fact which requires trial. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 1349, 89 L. Ed. 2d 538 (1986). When making a summary judgment determination, the court must view the evidence and all justifiable inferences from the evidence in the light most favorable to the non-moving party. Zahodnick, 135 F.3d at 913; Halperin v. Abacus Tech. Corp., 128 F.3d 191, 196 (4th Cir. 1997). However, the party opposing summary judgment may not rest on mere allegations or denials, and the Court need not consider "unsupported assertions" or "self-serving opinions without objective corroboration." Evans v. Techs. Applications & Serv. Co., 80 F.3d 954, 962 (4th Cir. 1996); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-49, 106 S. Ct. 2505, 2510, 91 L. Ed. 2d 202 (1986).

To make out a claim for punitive damages under North Carolina law, the claimant bears the burden of showing that the defendant is liable for compensatory damages, and that there exists an aggravating factor relating to the compensated injury. N.C. Gen. Stat. § 1D-15(a) (2009). Furthermore, the claimant "must prove the aggravating factor by clear and convincing

evidence.” N.C. Gen. Stat. § 1D-15(b). The aggravating factors that warrant punitive damages in North Carolina include (1) fraud, (2) malice, and (3) willful or wanton conduct. N.C. Gen. Stat. § 1D-15(a). Additionally, when the claimant seeks punitive damages against a corporation, the claimant must show that “the officers, directors, or managers of the corporation participated in or condoned the conduct constituting the aggravating factor giving rise to punitive damage.” N.C. Gen. Stat. § 1D-15(c).

In this case, Plaintiff has not alleged a claim based upon fraud or malice. Instead, Plaintiff has alleged that Defendant, through its officers, directors, or managers, engaged in willful or wanton conduct. The North Carolina punitive damages statute defines “willful or wanton” conduct as

the conscious and intentional disregard of and indifference to the rights and safety of others, which the defendant knows or should know is reasonably likely to result in injury, damage, or other harm. “Willful or wanton conduct” means more than gross negligence.

N.C. Gen. Stat. § 1D-5 (2009). The North Carolina Court of Appeals has further defined conduct as “willful” where there exists a “‘deliberate purpose not to discharge a duty . . . necessary for the safety of the person or property of another’” and conduct as “wanton” when “‘done needlessly, manifesting a reckless indifference to the rights of others.’” Cockerham-Ellerbee v. Town of Jonesville, 190 N.C. App. 150, 153, 660 S.E.2d 178, 180 (2008) (citations omitted), rev. denied, 362 N.C. 680, 669 S.E.2d 745 (2008).

When the claimant’s substantive evidentiary burden requires proof by clear and convincing evidence, as does a claim for punitive damages under North Carolina law, courts

must make a summary judgment ruling after “view[ing] the evidence presented through the prism of the substantive evidentiary burden.” Anderson, 477 U.S. at 254, 106 S. Ct. at 2513. Therefore, in this case, “the appropriate summary judgment question will be whether the evidence in the record could support a reasonable jury finding either that the plaintiff has shown [willful or wanton conduct] by clear and convincing evidence or that the plaintiff has not.” Id. at 255-56, 106 S. Ct. at 2514.

III. THE PARTIES’ EVIDENCE

In this case, Defendant contends that Plaintiff has produced no evidence that Defendant acted willfully or wantonly in relation to Mrs. Fussman’s alleged injury. Defendant claims that, after such time as it received reports asserting a possible link between ONJ and treatment with Aredia and Zometa, Defendant took steps to “obtain clinical information about ONJ, to understand what, if any, relationship it had to Zometa or Aredia, and to determine the best way to disseminate clinically relevant and reliable information to prescribing physicians and patients.” Defendant contends that its efforts included providing information regarding ONJ on its drug labels, drafting and disseminating clinical practice documents, or “White Paper,” and distributing “Dear Doctor” letters. Defendant further claims that its efforts during the time period in question complied with FDA guidelines. As such, Defendant argues that no genuine issue of material fact exists with respect to Plaintiff’s claim for punitive damages because Plaintiff has failed to produce any evidence showing that Defendant’s actions would constitute willful or wanton conduct.

In response, Plaintiff has submitted over 150 documents to support his contention that

Defendant willfully or wantonly took steps to conceal or misrepresent information regarding the alleged link between ONJ and Aredia and Zometa. Much of Plaintiff's evidence focuses on the information provided on the precaution labels for Aredia and Zometa. Specifically, Plaintiff alleges that Defendant included on the precaution labels a statement that cases of ONJ had been reported, but further noted that ONJ has "well documented" other risk factors unrelated to treatment with bisphosphonates. Plaintiff's evidence includes external communications to and internal communications among various Novartis employees about the nature of the "other" risk factors. These particular communications purport to show that Defendant was aware that there was not any scientific support for what Defendant contends was a connection between ONJ and the "well documented" risk factors described in the precaution labels. In addition, Plaintiff's evidence includes communications attributed to Defendant and its research documents which purport to show an alleged increase in scientific support for a connection between ONJ and treatment with bisphosphonates such as Aredia and Zometa. Plaintiff has also submitted evidence purporting to show that Defendant omitted from its dissemination of information relevant pieces of the ONJ research by allegedly controlling the membership of and the ultimate publications from advisory panels issuing opinions on the drugs at issue. Plaintiff's evidence also raises the concern that Defendant allegedly limited the scope of its employee communications with the medical community regarding ONJ and Defendant's prescription drugs. Finally, Plaintiff has submitted various documents purporting to show that Defendant knew of but ignored instances of ONJ reported in the clinical trials for Aredia and Zometa, and thereafter, Defendant allegedly failed to re-investigate the findings of the clinical trials once reports of ONJ

began to surface. Plaintiff argues that this evidence supports its claim that Defendant knew of but, in the face of alleged scientific support, refused to acknowledge that a connection existed between treatment with its drugs Aredia and Zometa and the reported incidents of ONJ. Plaintiff further argues that the evidence supports its claim that Defendant acted to promote alternative medical risk factors as the causal links to ONJ, knowing there existed a lack of scientific support, in order to direct attention away from the reported association between ONJ and Defendant's prescription drugs. As such, Plaintiff contends that sufficient evidence exists that would allow a jury to find by clear and convincing evidence that Defendant acted willfully or wantonly.¹

IV. DISCUSSION

The two parties rely on a number of cases to support their respective positions. First, Defendant relies primarily on Strawbridge v. Sugar Mountain Resort, 320 F. Supp. 2d 425 (W.D.N.C. 2004), and Schenk v. HNA Holdings, Inc., 170 N.C. App. 555, 613 S.E.2d 503 (N.C. Ct. App. 2005) for the assertion that Plaintiff's evidence is not sufficient to show that Defendant

¹ Defendant asserts that Plaintiff cannot succeed on a punitive damages claim in this case because he has not presented sufficient evidence that the allegedly willful or wanton actions at issue were taken by officers, directors, or managers of Novartis Pharmaceuticals Corporation pursuant to North Carolina General Statute Section 1D-15(c). The statute itself does not define the terms "officer," "director" or "manager" in its language. Id. In the absence of a statutory definition, the North Carolina Court of Appeals, in Wallace v. M, M & R, Inc., interpreted the word "manager" under its plain meaning as "one who 'conducts, directs, or supervises something.'" 165 N.C. App. 827, 832, 600 S.E.2d 514, 517-18 (2004) (quoting Webster's Third International Dictionary 1372 (1968)) (finding a restaurant manager with supervisory and hiring powers was a "manager" for purposes of the punitive damages statute). Plaintiff has therefore forecast sufficient evidence to survive summary judgment on whether the alleged actors for Defendant were at the very least "managers" within the meaning of North Carolina law.

acted wilfully or wantonly in this case.

In Strawbridge, the plaintiff, who was injured by falling on an allegedly bare portion of a ski slope, argued that the defendant ski resort engaged in willful and wanton conduct by misrepresenting how much snow was on the mountain, failing to mark bare areas on the ski slopes after injuries had been reported, and deliberately misstating the law to prevent skiers from bringing legal action against the resort. Strawbridge, 320 F. Supp. 2d at 436. The court first found that no evidence existed to support the plaintiff's claim that the defendant had deliberately misstated the law to its patrons. Id. Then the court noted that the defendant's alleged conduct of "failing to mark bare spots after hearing reports that they were causing injuries and exaggerating the amount of snow on the mountain" did not rise to the level of willful and wanton conduct, ultimately granting summary judgment for the defendant. Id. at 436.

Defendant's reliance on Strawbridge is based almost entirely on the fact that the underlying claim in Strawbridge, as in the present case, is failure to warn of an allegedly known danger. However, outside of that comparison, Strawbridge does not provide a highly analogous fact pattern under which Plaintiff's evidence can be measured. While the plaintiff's evidence in Strawbridge suggests that defendant was aware that there were likely bare spots on the mountain due to injury reports and recent weather conditions, the evidence in that case is somewhat distinguishable from the assertions by Plaintiff here that Defendant willfully or wantonly concealed relevant information with a reckless disregard for the safety of others. As such, the Court is not persuaded at all that Strawbridge controls the outcome in the present case.

Defendant also relies upon Schenk, which is factually somewhat closer to the present

case. In Schenk, the plaintiffs alleged harm from prolonged asbestos exposure and argued that the defendants acted willfully or wantonly where one of the defendant's engineers destroyed a memorandum regarding concerns with insulation removal practices. Schenk, 170 N.C. App. at 558, 560, 613 S.E.2d at 507. The plaintiffs in Schenk further asserted that the defendant employed a non-recommended procedure for asbestos removal which included certain violations of OSHA regulations relating to asbestos. Id. at 558, 561, 613 S.E.2d at 507-08. The court then found that destroying the memorandum was not willful or wanton where the engineer requested instead to be informed of all safety matters verbally, particularly where there was no evidence that the memorandum related to plaintiffs' injuries since the insulation removal practices outlined in the memorandum were not necessarily connected to asbestos. Id. at 560-61, 613 S.E.2d at 507-08. The court further found that the engineer who destroyed the memorandum was not an officer, director, or manager in the corporation, and thus punitive damages could not be imputed on the defendant corporation based on the engineer's action. Id. at 560, 613 S.E.2d at 507. In addition, the court found that while any alleged violation of the federal regulations at issue could be used to support a finding of negligence, it would not, by itself, support a finding of willful or wanton conduct. Id. at 561-62, 613 S.E.2d at 508-09. Ultimately, the court found that given the plaintiff's evidence, and evidence that defendant had asbestos training sessions, provided masks to employees, and performed safety inspections, defendant's actions did not demonstrate willful or wanton conduct to warrant a finding of punitive damages. Id. at 562, 613 S.E.2d at 508-09.

As previously noted, in the present case, Defendants cite Schenk in part to support its

contention that Plaintiff's evidence failed to show that the alleged misconduct by Defendant has a connection to the injury about which Plaintiff complains. See also State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408, 422, 123 S. Ct. 1513, 1522-23, 155 L. Ed. 2d 585 (2003) (finding that alleged misconduct must have a "nexus to the specific harm suffered by the plaintiff). On this point, however, Schenk is distinguishable from the present case. In Schenk, the destroyed memorandum did not contain information necessarily relating to asbestos exposure, and thus destroying it showed no clear connection to the plaintiff's injury resulting from asbestos exposure. Conversely, in the present case, Plaintiff's evidence purports to show that the information and documentation that Defendant allegedly concealed or misrepresented does indeed relate specifically to the alleged link between ONJ, Plaintiff's injury, and Plaintiff's treatment with the prescription drugs Aredia and Zometa. Therefore, Plaintiff's evidence purporting to show that Defendant concealed or misrepresented information regarding ONJ does provide a potential connection to Plaintiff's injury. Furthermore, as discussed above, unlike the engineer's destruction of the memorandum in Schenk, Plaintiff's evidence purports to show that Defendant's alleged actions to conceal or misrepresent information were undertaken by officers, directors, or managers of Novartis. Therefore, any alleged misrepresentation or concealment of information could be imputed to the Novartis Corporation if proven by Plaintiff's proposed evidence.

Finally, in distinguishing Schenk, it is to be noted that the court found there that there was no willful or wanton conduct based upon the recognition that the defendant posted general federal safety regulations for employees to read, provided employees with training about

asbestos removal, and provided protective masks to wear during removal efforts. Absent an analogous showing here in the present case, particularly viewing the evidence in the light most favorable to Plaintiff, the Court finds there exists a genuine issue of material fact as to whether Defendant engaged in comparable conduct to that relied upon in Schenk which could warrant a similar finding that Defendant did not act wilfully or wantonly. However, Defendant's assertions that it complied with FDA regulations in the labeling process, for example, while potentially probative on the issues of liability and punitive damages, are not dispositive as to either liability or punitive damages, and would therefore not preclude a claim for punitive damages. See Wyeth v. Levine, 129 S. Ct. 1187, 1203-04, 173 L. Ed. 2d 51 (2009) (finding that FDA approval does not necessarily preempt state law failure to warn claims).

Based on the foregoing, Defendant, as the moving party, has failed to meet its burden of showing that there exists no genuine issue of material fact as to punitive damages in this case. On the other hand, Plaintiff has presented evidence suggesting that a genuine issue of material fact does exist as to whether Defendant's alleged actions rise to the level of willful or wanton conduct. In support of his position, Plaintiff relies primarily on Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378 (4th Cir. 1995), for the assertion that he has presented sufficient evidence to show Defendant acted wilfully or wantonly. In Benedi, the Fourth Circuit applied Virginia law² to find that the plaintiff had forecast sufficient evidence to submit the question of punitive damages to

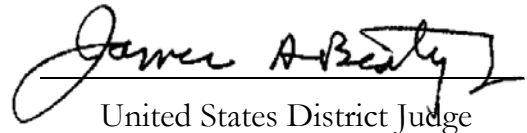
² Virginia law, similar to North Carolina, defines willful or wanton conduct as that which "evinces a conscious disregard of the rights of others." Benedi, 66 F.3d at 1389 (quoting Booth v. Robertson, 374 S.E.2d 1, 3 (Va. 1988)). Benedi further discusses such willful or wanton conduct in terms of "reckless indifference", id., just as the North Carolina Court of Appeals has done. See Cockerham-Ellerbe, 190 N.C. App. at 153, 660 S.E.2d at 180.

the jury. The plaintiff, alleging injury from failure to warn of the dangers associated with mixing Tylenol with alcohol, produced evidence that defendant failed to give the FDA years of case reports until after the FDA had issued a decision on the need for warnings. Benedi, 66 F.3d at 1389. The Plaintiff also demonstrated that the defendant instructed its sales representatives to refrain from discussing with physicians a scholarly article relating to the harm at issue. Id. Finally, the plaintiff in Benedi provided evidence that the defendant sent a letter to medical professionals stating that there was no link between the use of the drug and the harm caused. Id. Based upon these allegations, the Benedi case is the most factually analogous to the present case of the cases cited by either Plaintiff or Defendant. This is so, not only because it involves failure to warn in the prescription drug context, but because the alleged conduct by the defendants in Benedi as set out above and the alleged conduct by Novartis share similarities based on the evidence produced by Plaintiff. As stated above, Plaintiff has forecast evidence of communications purporting to show that Defendant allegedly concealed or misrepresented information regarding risk factors and clinical trial findings, controlled the flow of information about the alleged link between its prescription drugs and ONJ allegedly at the expense of truthful and complete disclosure, and Defendant refused to acknowledge a link between ONJ and treatment with Aredia and Zometa in spite of evidence to the contrary. Taken together, the Court finds Plaintiff's evidence at the very least does create a genuine issue of material fact as to whether Defendant acted wilfully or wantonly, by clear and convincing evidence, with regard to Plaintiff's failure to warn claims.

V. CONCLUSION

The Court finds that a genuine issue of material fact exists as to the punitive damages claims such that the evidence, viewed in the light most favorable to Plaintiff as the non-moving party, would support a reasonable jury finding willful or wanton conduct on the part of Defendant by clear and convincing evidence. Accordingly, for the reasons stated above, IT IS ORDERED that Defendant's Motion to Preclude Plaintiff's Demand for Punitive Damages [Doc. # 57] is DENIED.

This, the 25th day of October, 2010.


United States District Judge